General

Guideline Title

Breast reconstruction following prophylactic or therapeutic mastectomy for breast cancer.

Bibliographic Source(s)

Alberta Provincial Breast Tumour Team. Breast reconstruction following prophylactic or therapeutic mastectomy for breast cancer. Edmonton (Alberta): CancerControl Alberta; 2013 Sep. 47 p. (Clinical practice guideline; no. BR-016). [208 references]

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Recommendations

Major Recommendations

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

1. Eligibility for post-mastectomy breast reconstruction. Patients who are to undergo either prophylactic or therapeutic mastectomy should have access to breast reconstruction consultation.
   Various patient and treatment factors affect options, risks, and outcomes of a woman's breast reconstruction. Consultation with a specialist in breast reconstruction can provide a patient with a specialized treatment plan and anticipated outcomes so she can determine if breast reconstruction is appropriate for her. Table 1 in the original guideline document presents factors which may limit options and outcomes of breast reconstruction.

2. Types of breast reconstruction
   - Several types of breast reconstruction are available, including: implant-based, autologous flap (i.e., deep inferior epigastric perforator [DIEP], transverse rectus abdominis musculocutaneous [TRAM], superficial inferior epigastric artery [SIEA]), and combination reconstructions (i.e., latissimus dorsi [LD] with implant).
   - There is no evidence to suggest that one type of procedure can be recommended over another. The decision as to which type of reconstruction to use should be left to the discretion of the surgeons and the patient after providing counseling on the benefits and limitations of each procedure. Table 1 in the original guideline document presents factors which may influence the type of reconstruction to be performed.
3. Timing of breast reconstruction (immediate versus delayed)
   - Patients undergoing prophylactic mastectomy should be considered for immediate breast reconstruction (i.e., at the time of surgery).
   - Patients undergoing therapeutic mastectomy who do not require post-mastectomy radiotherapy should be considered for immediate breast reconstruction. There is sufficient evidence to support the oncologic safety of immediate reconstruction in these patients.

- Patients for whom radiotherapy is planned or highly likely should be discussed for breast reconstruction appropriateness in a multidisciplinary setting; in general, reconstruction should be delayed until after treatment with radiotherapy has been completed.
    - In patients where the likelihood of radiotherapy after mastectomy is uncertain (e.g., clinically staged node negative T1 or T2 tumours), an "upfront" staging sentinel lymph node biopsy (SLNB) could be considered as a separate, outpatient procedure to assist in determining the probability of post-mastectomy radiotherapy prior to proceeding with mastectomy and immediate reconstruction.
    - Data on the benefits and limitations of an "upfront" SLNB is limited to retrospective case series only. Until randomized data is available to compare "upfront" staging with intraoperative staging using frozen section analysis, one strategy cannot be recommended over another.
- Patients receiving other therapies, including chemotherapy, can be safely offered breast reconstruction with no evidence of adverse effects on the outcome of reconstruction and no clinically relevant delay in chemotherapy or adverse effect on the efficacy of chemotherapy.
- Patients for whom immediate breast reconstruction is not appropriate may be considered for delayed breast reconstruction as an acceptable alternative.

4. Factors that can affect the outcomes of breast reconstruction (see Table 1 in the original guideline document). Factors that should be weighed when considering candidates for any breast reconstruction (immediate or delayed) include:
    - Treatment factors: prior, concurrent, or known future breast cancer treatment
    - Patient factors: co-morbidities, body habitus, smoking status, behavioral/lifestyle factors
    - Cancer factors: tumour stage and location, risk of relapse
5. Extent of mastectomy (i.e., skin-sparing, nipple-sparing)
    - Skin-sparing mastectomy is acceptable for any patient undergoing immediate breast reconstruction.
    - Nipple-sparing mastectomy is generally not recommended for patients with malignancy. The decision as to whether to pursue a nipple-sparing procedure requires multidisciplinary input and discussion between the surgeons and the patient about potential additional risks associated with this approach.
    - There is limited evidence around what surgical factors to consider when performing mastectomy; however, based on consensus of the guideline working group, a list of technical considerations is included in Appendix A in the original guideline document.
6. Risks and benefits of breast reconstruction
    - Patients should be made aware that breast reconstruction is a complex, major, multi-step surgery and that complications can occur with any reconstruction.
    - Patient expectations should be assessed prior to surgery, in order to optimize care. In addition, patients should be made aware that cosmetic results may vary from patient to patient and that the reconstructive surgery will not restore the breast to its original appearance.
    - Complications can occur with each type of reconstructive procedure. Listed below are the most common complications associated with each procedure:
        - Autologous reconstructions: seroma, scarring, hematoma, chronic back pain, flap failure, abdominal weakness, bulge, or hernia, and necrosis. There is evidence to suggest that DIEP flaps carry a higher risk of fat necrosis and flap loss, as compared to muscle-sparing TRAM flaps. There is also evidence to suggest that donor-site morbidity (i.e., bulge formation, hernia) is lower with DIEP flaps, as compared to muscle-sparing TRAM flaps.
        - Implant-based reconstructions: mastectomy skin flap necrosis, infection, seroma, hematoma, chronic breast pain, implant rupture or malposition, and capsular contracture. There is evidence to suggest that the risk of capsular contracture is lower with the use of textured implants, as compared to smooth implants.
7. Post-breast reconstruction surveillance. There is no evidence to support routine screening mammography of the reconstructed breast, in the absence of a palpable recurrence or symptoms of recurrence. Fat necrosis is a common and benign mammographic finding in patients with reconstructed breasts. Patients with suspicious masses or symptoms should be referred to a surgeon for examination and further workup.
8. Implant-based acellular dermal matrix reconstructions
    - The use of human acellular dermal matrix (HADM) in immediate prosthetic breast reconstruction confers the potential benefits of improved aesthetic results, reduced rates of capsular contracture and implant malposition, and the possibility of a single-stage "direct to implant" procedure for carefully selected patients.
    - These benefits should be weighed against the potentially higher risks of postoperative seroma, infection, and mastectomy skin flap necrosis in HADM-assisted prosthetic reconstruction, when compared to traditional, non HADM-assisted techniques.
    - Based on consensus, the use of HADM in breast reconstruction should be at the discretion of the reconstructive surgeon, in consultation with the patient and oncologic team. Indications to use HADM include two-stage expander implant reconstruction or direct to implant single-stage reconstruction, to gain increased control over infra- and lateral mammary fold position and ptosis.
9. Adjunctive autologous fat grafting (lipofilling) for contour regularities after breast reconstruction. There is currently limited data on the long-

term oncologic safety and long-term contour benefits of lipofilling. Data from comparative studies and case reports suggest that patient satisfaction is good; however more data is needed.

Clinical Algorithm(s)

An algorithm titled "Algorithm for the Use of Breast Reconstruction in Patients Undergoing Mastectomy" is provided in the original guideline document.

Scope

Disease/Condition(s)

Breast cancer

Guideline Category

Management

Treatment

Clinical Specialty

Obstetrics and Gynecology

Oncology

Plastic Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide physicians in Alberta with recommendations on the selection of candidates for breast reconstruction, the decision on how much tissue to remove during mastectomy, the timing of reconstruction procedures, the selection of an appropriate reconstruction, and the impact of breast reconstruction on adjuvant therapy

Target Population

Women over the age of 18 years who are candidates for mastectomy, either for the treatment of breast cancer or for the prophylaxis of breast cancer in patients at high genetic risk

Interventions and Practices Considered

1. Assessment of patient eligibility for post-mastectomy breast reconstruction
2. Choice of type of breast reconstruction: implant-based, autologous flap (i.e., deep inferior epigastric perforator [DIEP], transverse rectus abdominis musculocutaneous [TRAM], superficial inferior epigastric artery [SIEA]), and combination reconstructions (i.e., latissimus dorsi [LD] with implant)
3. Timing of breast reconstruction (immediate versus delayed)
4. Consideration of treatment, patient, and cancer factors that can affect outcomes of breast reconstruction
5. Consideration of extent of mastectomy (i.e., skin-sparing, nipple-sparing)
6. Discussing risks and benefits of breast reconstruction with the patient
7. Post-breast reconstruction surveillance
8. Use of human acellular dermal matrix (HADM) in immediate prosthetic breast reconstruction
9. Use of adjunctive autologous fat grafting (lipofilling) for contour regularities after breast reconstruction

Major Outcomes Considered

- Aesthetic outcomes
- Short- and long-term complications
- Overall patient satisfaction
- Cost-effectiveness
- Local recurrence rate
- Failure rate
- Quality of life
- Psychological morbidity

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Research Questions

Specific research questions to be addressed by the guideline document were formulated by the guideline lead(s) and Knowledge Management (KM) Specialist using the PICO question format (patient or population, intervention, comparisons, outcomes).

Guideline Questions

The questions below are consensus-based and were derived from a discussion among the members of the guideline working group.

1. Who is a candidate for post-mastectomy breast reconstruction?
2. Which types of breast reconstruction are available?
3. What is the appropriate timing of breast reconstruction?
4. Which factors can affect the outcomes of breast reconstruction?
5. What is appropriate extent of mastectomy (i.e., skin-sparing, nipple-sparing)?
6. What are the risks and benefits associated with breast reconstruction?
7. What is the appropriate post-breast reconstruction surveillance?
8. What is the role of acellular dermal matrix in implant-based breast reconstruction?
9. What is the role of autologous fat grafting as an adjunct to breast reconstruction?

Search Strategy

The PubMed and EMBASE databases were searched from 1980 to 2012 May 30 for literature on breast reconstruction following prophylactic or therapeutic mastectomy. The search terms *breast reconstruction* and *cancer* or *neoplasm* were used and results were limited to randomized controlled trials, prospective and retrospective cohort studies, meta-analyses, guidelines, and reviews, published in English. The search returned 223 citations, of which 74 were relevant. Prior to publication, the search was extended to 2013 April 20 resulting in an additional eight relevant studies. In addition, reference lists of publications identified by the search were hand-searched for additional publications, resulting in 97 additional citations.

Based on post-hoc discussions among the working group, two subsequent searches of literature were conducted. PubMed was searched for literature on the integration of reconstruction with sentinel lymph node biopsy and of the impact of chemotherapy on breast reconstruction. Both searches were limited to English language publications but were not limited by study design. A total 11 citations on sentinel lymph node biopsy and 12 citations on chemotherapy were deemed relevant.

The National Guideline Clearinghouse and Standards and Guidelines Evidence (SAGE) Directory of Cancer Guidelines were also searched from 2006 to June 15, 2012 for guidelines on breast reconstruction. The search returned 17 guidelines, of which seven were relevant. The guidelines, plus an additional guideline from PubMed, were included in the literature review. None of these published guidelines focused specifically and solely on breast reconstruction.

Number of Source Documents

Refer to the "Description of Methods Used to Collect/Select the Evidence" field.

Methods Used to Assess the Quality and Strength of the Evidence

Not stated

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Evidence was selected and reviewed by a working group comprised of members from the Alberta Provincial Breast Tumour Team, a province-wide working group of plastic surgeons, and a Knowledge Management Specialist from the Guideline Utilization Resource Unit (GURU). A detailed description of the methodology followed during the guideline development process can be found in the Guideline Utilization Resource Unit Handbook (see the "Availability of Companion Documents" field).

Evidence Tables

Evidence tables containing the first author, year of publication, patient group/stage of disease, methodology, and main outcomes of interest are assembled using the studies identified in the literature search. Existing guidelines on the topic are assessed by the KM Specialist using portions of the Appraisal of Guidelines Research and Evaluation (AGREE) II instrument (http://www.agreetrust.org) and those meeting the minimum requirements are included in the evidence document. Due to limited resources, GURU does not regularly employ the use of multiple reviewers to rank the level of evidence; rather, the methodology portion of the evidence table contains the pertinent information required for the reader to judge for himself the quality of the studies.

A complete summary of the evidence is provided in table form in Appendix B in the original guideline document.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Formulating Recommendations

The working group members formulated the guideline recommendations based on the evidence synthesized by the Knowledge Management (KM) Specialist during the planning process, blended with expert clinical interpretation of the evidence. As detailed in the Guideline Utilization Resource Unit Handbook (see the "Availability of Companion Documents" field), the working group members may decide to adopt the recommendations of another institution without any revisions, adapt the recommendations of another institution or institutions to better reflect local practices, or develop their own set of recommendations by adapting some, but not all, recommendations from different guidelines.

The degree to which a recommendation is based on expert opinion of the working group and/or the Provincial Tumour Team members is explicitly stated in the guideline recommendations. Similar to the American Society of Clinical Oncology (ASCO) methodology for formulating guideline recommendations, the Guideline Utilization Resource Unit (GURU) does not use formal rating schemes for describing the strength of the recommendations, but rather describes, in conventional and explicit language, the type and quality of the research and existing guidelines that were taken into consideration when formulating the recommendations.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Cost-effectiveness

Overall, patient outcomes are good, regardless of the type of reconstruction used. In terms of cost, statistics from the U.S. from 2008 revealed a $2,860 difference mean lifetime cost (including initial hospitalization and complications and revisions up to one year) in favor of a free transverse rectus abdominis myocutaneous (TRAM) flap ($14,080) over an implant ($16,940); however the cost difference disappeared over time. A Canadian study comparing deep inferior epigastric perforator (DIEP) and TRAM flap reconstructions, using a cost-effectiveness analysis incorporating medical costs (inpatient costs only) from the Ontario Ministry of Health (2002), showed that the DIEP flap was slightly more costly than the free TRAM flap ($7,026.47 versus $6,508.29) while providing similar quality-adjusted life years (QALYs) to the free TRAM flap (28.88 years versus 28.53 years). Furthermore, the baseline incremental cost-utility ratio was $1,464.30 per QALY, favoring adoption of the DIEP flap. Sensitivity analyses accounting for the incidence of hernia, abdominal bulging, total flap loss, operating room time, and hospital stay were identical between the DIEP and free TRAM procedures. However, increasing the probability of abdominal bulge from 0.041 to 0.103 for the DIEP flap changed the ratio to $2,731.78 per QALY; increasing the probability of total flap failure from 0.014 to 0.016 changed the ratio to $1,384.01 per QALY; assuming the time in the operating room to be the same for both flaps changed the ratio to $4,026.57 per QALY; and finally, assuming the hospital stay to be the same for both flaps, changed the ratio to $1,944.30 per QALY. It has been reported elsewhere, however, that the cost of a latissimus dorsi, TRAM, or DIEP flap reconstructions, including both primary surgery and any revisions, are similar, and that any small financial benefits gained from the implant reconstruction at initial surgery will be lost over time, as patients require additional revisions. As such, no recommendations can be made, favoring one type of reconstruction over another from a cost perspective. The decision to use an implant or an autologous flap, or to use a latissimus dorsi or TRAM or DIEP flap should be left to the discretion of the plastic surgeon and the patient after counseling the patient on the benefits and limitations of each type of available reconstruction.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This guideline was reviewed and endorsed by the Alberta Provincial Breast Tumour Team.

When the draft guideline document has been completed, revised, and reviewed by the Knowledge Management Specialist and the working group members, it is sent to all members of the Provincial Tumour Team for review and comment. This step ensures that those intended to use the guideline have the opportunity to review the document and identify potential difficulties for implementation before the guideline is finalized. Depending on the size of the document, and the number of people it is sent to for review, a deadline of one to two weeks will usually be given to submit any feedback. Ideally, this review will occur prior to the annual Provincial Tumour Team meeting, and a discussion of the proposed edits will take place at the meeting. The working group members will then make final revisions to the document based on the received feedback, as appropriate. Once the guideline is finalized, it will be officially endorsed by the Provincial Tumour Team Lead and the Executive Director of Provincial Tumour Programs.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Breast reconstruction may alleviate some of the post-mastectomy distress experienced by patients who have undergone mastectomy.

Potential Harms

- As with any major surgery, complications can occur with breast reconstruction. The most common complications associated with autologous flap reconstructions are flap necrosis (~5% of patients), infections (~5% of patients), and seroma (~4% of patients). Reoperation is often required in patients who develop flap necrosis. Less common complications from autologous breast reconstruction include bruising and bleeding and chronic pain. Deep inferior epigastric perforators (DIEP) flaps have been shown to carry a higher risk of fat necrosis, flap loss, but lower donor-site morbidity (i.e., bulge formation, hernia), as compared to muscle-sparing transverse rectus abdominis myocutaneous (TRAM) flaps.
- In patients who undergo implant-based breast reconstruction with human acellular dermal matrix (HADM), the total complication rate is about 15% and the most common complications are mastectomy flap necrosis (~7% of patients), infection (~5% of patients), and seroma (~5% of patients). Mastectomy flap necrosis can necessitate removal of the implants and reoperation. As with autologous reconstruction, implant-based reconstruction may be associated with bruising and bleeding, chronic pain, implant rupture or malposition, and capsular contracture, which more frequently occurs in patients who undergo radiation therapy. There is evidence to suggest that the risk of capsular contracture is lower with the use of textured implants, as compared to smooth implants. In a very small group of patients with implants, anaplastic large cell lymphoma (ALCL) has been observed. By 2007, only six cases of ALCL in the setting of breast implant surgery had been reported. By 2010, a total of 34 unique cases had been identified among an estimated 10 million women with breast implants and the majority of these 34 patients are still alive and well. The United States Food and Drug Administration then conducted an investigation and concluded that: (1) there is a possible association between ALCL and breast implants, adding that although the incidence is low, the occurrence of ALCL in patients with implants may not be a coincidence; (2) it is not possible to identify a specific type of implant that is associated with a higher or lower risk of ALCL; and (3) the true cause of ALCL in patients with implants is unknown. Subsequently, the American Society of Plastic Surgeons and the American Society for Aesthetic Plastic Surgery issued a statement indicating that ALCL is extremely rare, that the risk of women with implants developing ALCL is extremely low, and that breast implants are safe and effective.

Qualifying Statements

Qualifying Statements

Qualifying Statements

The recommendations contained in this guideline are a consensus of the Alberta Provincial Breast Tumour Team and are a synthesis of currently accepted approaches to management, derived from a review of relevant scientific literature. Clinicians applying these guidelines should, in consultation with the patient, use independent medical judgment in the context of individual clinical circumstances to direct care.

Implementation of the Guideline

Description of Implementation Strategy

- Present the guideline at the local and provincial tumour team meetings and weekly rounds.
- Post the guideline on the Alberta Health Services Web site.
- Send an electronic notification of the new guideline to all members of CancerControl Alberta.
- Publish the guideline in a peer-reviewed journal.

Implementation Tools

Clinical Algorithm

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Alberta Provincial Breast Tumour Team. Breast reconstruction following prophylactic or therapeutic mastectomy for breast cancer. Edmonton (Alberta): CancerControl Alberta; 2013 Sep. 47 p. (Clinical practice guideline; no. BR-016). [208 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Sep

Guideline Developer(s)

CancerControl Alberta - State/Local Government Agency [Non-U.S.]

Source(s) of Funding

CancerControl Alberta

Guideline Committee

Alberta Provincial Breast Tumour Team

Composition of Group That Authored the Guideline

Members of the Alberta Provincial Breast Tumour Team include medical oncologists, radiation oncologists, surgeons, nurses, pathologists, psychologists, and pharmacists.

Financial Disclosures/Conflicts of Interest

Participation of members of the Alberta Provincial Breast Tumour Team in the development of this guideline has been voluntary and the authors have not been remunerated for their contributions. There was no direct industry involvement in the development or dissemination of this guideline. CancerControl Alberta recognizes that although industry support of research, education and other areas is necessary in order to advance patient care, such support may lead to potential conflicts of interest. Some members of the Alberta Provincial Breast Tumour Team are involved in research funded by industry or have other such potential conflicts of interest. However the developers of this guideline are satisfied it was developed in an unbiased manner.

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Guideline Availability

Available from the Alberta Health Services Web site.

Availability of Companion Documents

The following is available:

- Guideline utilization resource unit handbook. Edmonton (Alberta): CancerControl Alberta; 2013 Jan. 5 p. Electronic copies: Available from the Alberta Health Services Web site.

In addition, Appendix A in the original guideline document lists technical issues relevant to different types of breast reconstruction.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on August 12, 2014. The information was verified by the guideline developer on September 22, 2014.

Copyright Statement

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